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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,536	01/22/2002	Nobutaka Wakamiya	19036/36614A	7209
4743	7590	06/29/2005	EXAMINER	
MARSHALL, GERSTEIN & BORUN LLP 233 S. WACKER DRIVE, SUITE 6300 SEARS TOWER CHICAGO, IL 60606			DEVI, SARVAMANGALA J N	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/054,536		WAKAMIYA, NOBUTAKA	
	Examiner		Art Unit	
	S. Devi, Ph.D.		1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO APPLICANT'S AMENDMENT

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' amendment filed 04/11/05 in response to the non-final Office Action mailed 10/06/04. With this, Applicant's has amended the specification.

Status of Claims

- 2) Claims 1-13 have been canceled via the amendment filed 04/11/05.
New claims 14-17 are added via the amendment filed 04/11/05.
Claims 14-17 are pending and are under examination.

Prior Citation of Title 35 Sections

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

The Wakamiya Declaration

- 5) Acknowledgment is made of Applicant's submission of the Wakamiya declaration filed 04/11/05 under 37 C.F.R 1.132. The declaration has been fully considered. The declarant states that the work summarized in the publication by Ohtani *et al.* is a description of his invention and not that of the other co-authors. The declarant states that he conceived the project described in the publication and of how to carry it out, and that others did not make a substantial contribution to the invention, but worked under his direction and supervision.

Objection(s) Withdrawn

- 6) The objection to the Oath/Declaration made in paragraph 5 of the Office Action mailed 12/30/04 is withdrawn in light of Applicant's submission of a new Oath/Declaration.
- 7) The objection to the specification made in paragraph 7 of the Office Action mailed

12/30/04 is withdrawn in light of Applicant's amendments to the specification.

Objection(s) Moot

8) The objection to claims 6 and 9 made in paragraph 5 of the Office Action mailed 12/30/04 is moot in light of Applicant's cancellation of the claims.

Rejection(s) Moot

9) The rejection of claims 6, 7 and 9-11 made in paragraph 9 of the Office Action mailed 12/30/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicant's cancellation of the claims.

10) The rejection of claim 11 made in paragraph 11 of the Office Action mailed 12/30/04 under 35 U.S.C § 102(a) as being anticipated by Ma *et al.* (*J. Biochem.* 122: 810-818, October 1997), is moot in light of Applicant's cancellation of the claim.

11) The rejection of claims 6, 7, 9 and 11 made in paragraph 12 of the Office Action mailed 12/30/04 under 35 U.S.C § 102(a) as being anticipated by Otani *et al.* (*Nippon Men'eki Gakkai Soaki, Gakujutsu Shukai Kiroku* 27: 182, 29 September 1997 – Original and English translation) as evidenced by Stanislawski *et al.* (US 2004/0170653), is moot in light of Applicant's cancellation of the claims.

New Rejection(s) Based on Applicant's Amendment

The new rejection(s) set forth below are necessitated by Applicant's amendment and/or submission of new claims.

Rejection(s) under 35 U.S.C § 112, First Paragraph

12) Claims 14, 17 and those dependent from claim 14, are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

New claim 14 includes the limitations, such as: 'successively culturing the cell in a medium containing neomycin and a medium containing methotrexate'; 'collecting rhMBP from the medium'; and 'the full length nucleotide sequence' set out in SEQ ID N: 2. However, these

cancelled claims do not appear to provide descriptive support for a generic 'medium'; for 'collecting rhMBP from the medium', and for the limitations: 'successively culturing the cell in a medium containing neomycin and a medium containing methotrexate'. The scope of the term 'culture medium' as recited in cancelled claims is not the same as the scope of the generic term 'medium'. There appears to be no descriptive support in the specification for 'the full-length' nucleotide sequence set out in SEQ ID N: 2. Claim 17 includes the limitations: 'method according to Claim 14, wherein said rhMBP inhibits hemagglutination by Influenza Viruses'. However, a method for producing rhMBP which includes inhibition of hemagglutination by Influenza Viruses is not supported in the instant specification. Therefore, the above-identified limitations in the claims are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicant is respectfully requested to point to the descriptive support in the specification as filed, for the newly added limitation(s), or to remove the new matter from the claim(s).

Rejection(s) under 35 U.S.C § 112, Second Paragraph

13) Claims 14-17 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

(a) Claim 14 lacks a preceding article before the limitation: 'Recombinant Human Mannan-Binding Protein (rhMBP)'. It is suggested that Applicant replace the limitation with --a. Recombinant Human Mannan-Binding Protein (rhMBP)--.

(b) In claim 14, in order to distinctly claim the subject matter and for clarity, it is suggested that Applicant replace the recitation 'set out in' with the limitation --of--.

(c) Claim 16 is indefinite and confusing in the limitations: 'said rhMBP has a peak molecular weight of about 1,000 kDa – about 1,300 kDa and about 200 kDa – about 400 kDa', because it is unclear how the pNOW1-hMBP expression vector comprising the full-length nucleotide sequence of SEQ ID NO: 2 can express rhMBP having a peak molecular weight of

about 1,000 kDa – about 1,300 kDa **and** about 200 kDa – about 400 kDa. Are these two rhMBP having two different molecular weight ranges? Clarification is requested.

(d) Claim 14 lacks proper antecedent basis in the limitation: ‘rhMBP’ in line 7 of the claim. For proper antecedence, it is suggested that Applicant replace the limitation with --the rhMBP--.

(e) Claim 14 is vague and/or incorrect in the limitation: ‘comprising steps of’. It is suggested that Applicant replace the phrase with --comprising--.

(f) Claim 17 is vague and confusing in the limitation: ‘method according to Claim 14, wherein said rhMBP inhibits hemagglutination by Influenza Viruses’. Claim 14 is drawn to a method of producing rhMBP comprising steps (a), (b) and (c), none of which involve hemagglutination or Influenza Viruses. It is unclear how or at which step ‘said rhMBP inhibits hemagglutination by Influenza Viruses’.

(g) Claim 14 is vague or confusing in the limitation: ‘a pNOW1-hMBP expression vector’. Does it mean that there are more than one pNOW1-hMBP expression vectors of which the recited vector is one?

(h) Claims 15-17, which depend from claim 14, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Remarks

14) Claims 14-17 stand rejected.

15) Applicant’s amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

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will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


16) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Central Fax number for submission of amendments, response and papers is (703) 872-9306.

17) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

June, 2005


S. DEVI, PH.D.
PRIMARY EXAMINER